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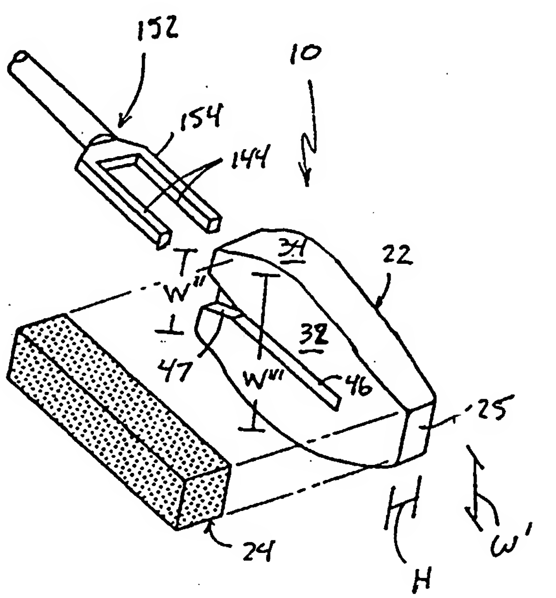
(54) Title: ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER



(57) Abstract: A middle expanded, removable disk implant for stabilizing adjacent vertebrae. The implant is substantially rectangular in cross-sectional shape with a minimal height and a width greater than the height. The implant is detachably mounted to an applicator for insertion into the space between two adjacent vertebrae from which a portion of the intervertebral disk has been removed. Once inserted, the implant is positioned by anterior-posterior movement in the disk space to the position in which both the expanded, larger width middle portion and the smaller end portions engage the bodies of the adjacent vertebrae and the implant is then rotated to bring the sides of the rectangularly-shaped implant defining the width of the implant, with its larger dimension, into engagement with the bodies of the vertebrae. A locking piece is then inserted into the disk space adjacent the rotated implant. The locking piece includes a surface for bearing against the bodies of the adjacent vertebrae to resist rotation of the locking piece along the longitudinal axis thereof and an implant bearing surface for engaging one of the sides of the implant defining the width of the implant to resist rotation of the implant relative to the locking piece. Both implant and locking piece are comprised of bone, the locking piece being preferably comprised of both cortical and cancellous bone, or the implant is comprised of metal, bio-compatible polymer, or other suitable material. The implant may also include a flared end for maintaining proper spinal curvature of the patient.

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ROTATING, LOCKING INTER-VERTEBRAL DISK STABILIZER

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of co-pending application Serial No. 09/561,483, filed April 28, 2000 and entitled ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER. Serial No. 09/561,483 is a continuation-in-part of co-pending application Serial No. 09/290,831, filed April 13, 1999 entitled ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER AND APPLICATOR. Serial No. 09/290,831 was a continuation of application Serial No. 08/900,174, filed July 25, 1997, also entitled ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER AND APPLICATOR, and which is now issued as Patent No. 5,893,890. Serial No. 08/900,174 was a continuation-in-part of then co-pending application Serial No. 08/475,211, filed June 6, 1995 and entitled ROTATING, LOCKING, MIDDLE-EXPANDED INTERVERTEBRAL DISK STABILIZER (as amended) and now issued as Patent No. 5,658,336. Serial No. 08/475,211 was a continuation-in-part of International Application No. PCT/US95/03374 entitled MIDDLE EXPANDED, REMOVABLE, INTERVERTEBRAL DISK IMPLANT AND METHOD OF LUMBAR INTERVERTEBRAL DISK STABILIZATION filed on March 17, 1995. International Application No. PCT/US95/03374 was itself a continuation-in-part of U.S. application Serial No. 08/210,229, filed March 18, 1994 and having that same title and now issued as Patent No. 6,093,207.

BACKGROUND OF THE INVENTION

The present invention relates to an intervertebral disk stabilizing implant for stabilizing two adjacent vertebrae. More specifically, the present invention relates to rectangularly-shaped disk implants which are expanded in the middle portion and are used for spinal fusion.

Treatment of a herniated disk in the neck and in the lumbar region continues to be a challenging field of medicine. The classical treatment for a ruptured disk is diskectomy, i.e., removal of the disk from between the vertebrae. In this process, all or a portion of the intervertebral disk is removed, leaving a defect which continues to bother the patients throughout the rest of their lives. An additional procedure is to replace the disk space with a bone graft, usually bone chips cut from the patient's iliac crest, bringing about fusion of the vertebrae above and below the disk and eliminating the empty space between the vertebrae.

Diskectomy with fusion is not ideal because the replaced bone does not have the function of the cartilaginous tissue of the disk, i.e. no cushioning effect, and has complications because of several factors. First, conventional bone plugs used to pack the disk space do not conform to the space of the disk because the disk bulges maximally in the center. The disk space is wider in the middle and narrower at its anterior and posterior ends. For this reason, the various bone plugs which are currently available commercially have only four contact points, i.e. at the front and back of the disk space. Secondly, access to the disk is from the side of the dorsal spine of the adjacent vertebrae, leaving a space that is "off-center" relative to the bodies of the adjacent vertebrae such that the stability of the implant is even more problematical than might be apparent from the limited contact resulting from the shape of the intervertebral space. Another complication is the possibility of infection or other conditions that may require removal of the implant. Also, if the bone pieces do not fuse, they may eventually extrude out of the disk space, causing pressure on the nerve roots.

Various prosthetic disk plugs, or implants, are disclosed in the art, but all are characterized by limitations of not conforming to the shape of the disk space, lack of stability when inserted off-center, inability to be removed, or other disadvantages. For instance, U.S. Patent No. 4,863,476 (and its European counterpart, EP-A-0260044) describes an elongated body divided longitudinally into two portions having a cam device movable therebetween for increasing the space between the two body portions once inserted into the disk space. However, that device is generally cylindrical in shape such that the only contact points between the device and the vertebral bodies are at the front and

back of the disk space, creating increased likelihood of instability and generally rendering that device unsuitable for use after partial diskectomy. The art also discloses intervertebral disk prostheses (e.g., U.S. Patent Nos. 3,867,728, 4,309,777, 4,863,477 and 4,932,969 and French Patent Application No. 8816184) which may have more general contact with the adjacent disks, but which are not intended for use in fusion of the disks. The art also includes spinal joint prostheses such as is described in U.S. Patent No. 4,759,769, which is again not indicated for use when fusion is the preferred surgical intervention.

Published PCT Application WO96/40016 discloses an intervertebral disk stabilizer having a lock that engages the end of the implant. There are, however, indications for use of an intervertebral stabilizer in which an increased likelihood of successful fusion can be obtained.

There is, therefore, a need for a device capable of stabilizing the vertebrae adjacent an intervertebral disk, but which is also removable, for use in spinal fusion. There is also a need for a method of implanting such a stabilizer.

Because of its desirable properties when used for fusion of adjacent vertebrae, there is also a need for an implant having these advantages but which also has a construction, or shape, that lends itself to being fabricated from bone.

SUMMARY OF THE INVENTION

These needs are met in the present invention by providing a vertebral disk stabilizer comprising an elongate implant of minimal height defined by first and second sides and maximal width defined by third and fourth sides, the third and fourth sides being arched from one end of the implant to the other to provide the portion intermediate the ends with a width larger than the width of the implant at the ends thereof. Also provided is a locking piece having an implant bearing surface formed thereon for engaging either the first or second sides of the implant to resist rotation of the implant relative to the stabilizer after the implant is inserted into the disk space between two adjacent vertebrae with the first and second sides of the implant contacting the bodies of the adjacent vertebrae and then rotated so that the third and fourth sides of the implant contact the adjacent vertebrae and the locking piece is likewise positioned in the disk space and a vertebral body bearing surface

oriented at approximately 90° to the implant bearing surface for engaging the body of the adjacent vertebrae when positioned in the disk space to resist rotation of the locking piece in the disk space.

The implant is inserted into the disk space with the implant oriented so that the first and second sides engage the bodies of the adjacent vertebrae. The implant is then rotated approximately 90° in the disk space so that the third and fourth sides contact the bodies of the adjacent vertebrae. The locking piece is then inserted into the disk space with the implant bearing surface engaging either the first or second sides of the implant to resist rotation of the implant relative to the stabilizer. The vertebral body bearing surface bears against the body of the adjacent vertebrae to resist rotation of the locking piece relative to the body of the adjacent vertebrae against which the surface of the locking piece bears.

In another aspect, the present invention provides an apparatus for use in fusing adjacent vertebrae comprising an elongate implant with two substantially planar faces and two opposed edges, each edge being arched from one end of the implant to the other, and a locking piece dimensioned to be located adjacent a single one of the planar faces and to resist rotation of the implant after the implant and the locking piece are inserted into a space between two vertebrae. At least one of the implant and the locking piece are made of bone. The implant is preferably comprised of cortical bone and the locking piece is preferably comprised of a central core of cancellous bone surrounded on three sides by a layer of cortical bone.

Also provided is a method of making an apparatus for use in fusing two vertebrae comprising the steps of forming a "blank" from cortical bone harvested from the femur by making two substantially parallel cuts in a section of the shaft of the femur and then forming the insert from the blank.

In another aspect, the present invention provides an apparatus for use in fusing adjacent vertebrae comprising an elongate implant to be located between adjacent vertebrae and having two opposed edges, each of arched form, the opposed edges being shaped such that an end part of the implant is flared so that a portion of the implant between the flared end part and the remainder of the implant is of lesser width than the width of the flare.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a lateral view of a portion of a human spinal column having a vertebral disk stabilizer constructed in accordance with the teachings of the present invention inserted therein and having a portion of the bodies of the vertebrae adjacent the implant shown cut away and/or in shadow lines to show the engagement of the vertebral bodies by the vertebral disk stabilizer.

Figure 2 is an enlarged, perspective, partially schematic view of the vertebral disk stabilizer of Fig. 1 in place between two adjacent vertebral bodies.

Figure 3 is a perspective view of the implant of the vertebral disk stabilizer of Figs. 1 and 2 and an applicator to which the implant is mounted for placing the implant in the position shown in Fig. 1.

Figure 4 is a perspective view of a human femur cut in cross-section to show a method of fabricating the implant of the vertebral disk stabilizer in accordance with the method of the present invention is fabricated.

Figure 5A is a partially schematic lateral elevational view of a portion of the human skeleton comprising the hip joint, the ilium, and a portion of the femur to show a method of fabricting the locking piece of the vertebral disk stabilizer in accordance with the method of the present invention.

Figure 5B is a perspective view of a portion of the iliac crest after cutting along the shadow lines in Fig. 5A.

Figures 6A, 6B, and 6C are elevational views of a second embodiment of an implant constructed in accordance with the teachings of the present invention.

Figure 7 is an elevational view of a third embodiment of an implant constructed in accordance with the teachings of the present invention.

Figure 8 is a perspective view of a fourth embodiment of an implant constructed in accordance with the teachings of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the figures, a first embodiment of a disk stabilizer constructed in accordance with the teachings of the present invention is shown implanted in a human

spinal column in Fig. 1. The vertebral disk stabilizer, indicated generally at reference numeral 10, is implanted between the bodies 12 and 14 of two adjacent vertebrae 16 and 18, respectively, in the disk space (not numbered) from which a portion of the intervertebral disk 20 is removed, i.e. by simple diskectomy and small laminotomy.

Referring now also to Figs. 2 and 3, the preferred embodiment of the vertebral disk stabilizer 10 of the present invention shown is comprised of an elongate implant 22 and locking piece 24. In more detail, implant 22 is comprised of first and second sides 32 and third and fourth sides 34 providing a substantially rectangularly shaped cross-section. The height H of the rectangularly shaped cross-section is defined by first and second sides 32 and the width W is defined by the third and fourth sides 34 and, as is apparent by comparison of H and W, the height of H of implant 22 is less than the width W. As will be explained below, H is minimized to facilitate insertion of the second end 36 into, and positioning of implant 22 in, the disk space from which a portion of the intervertebral disk 20 was removed and W is maximized to provide the desired stabilization to adjacent vertebrae 16 and 18. Third and fourth sides 34 are arched from one end of implant 22 to the other to provide the portion of implant 22 intermediate the ends 25 and 36 with a width W which is larger than the width W' and W" at the ends 25 and 36, respectively. By comparison of the widths at the ends and middle portions of implant 22, it can be seen that in the embodiment shown in Fig. 3, the width W' at the end 25 of implant 22 is less than the width W" at the end 36 of implant 22. Because the sides 32 of implant 22 are substantially flat and the sides 34 are arched from one end 25 to the other end 36, implant 22 is described as being a bi-planar, bi-convex implant.

In the embodiment shown in Figs. 1-3, both the implant 22 and locking piece 24 are comprised of bone that is harvested and fabricated in the manner described below. Those skilled in the art who have the benefit of this disclosure will recognize that implant 22 and locking piece 24 may also be comprised of materials such as metal or polymeric materials so long as the material comprising implant 22 and locking piece 24 is biologically inert and/or minimally objectionable to the body's normal physiological processes. Although not shown, in one embodiment, the bi-convex sides 34 of implant 22 are provided with a plurality of teeth for biting into the adjacent vertebrae 16 and 18. So as to provide

additional resistance to anterior-posterior (forward or backward) movement of implant 22 in the disk space, the teeth located closest to the end 25 of implant 22 (e.g., the teeth in the distal portion of implant 22) may be oriented at a slant toward the end 25 and the teeth closest to the end 36 of implant 22 may be oriented at a slant toward the end 36. The teeth in the middle portion of implant 22, e.g., between the two sets of slanted teeth, are then oriented vertically. It will also be recognized that the sides 34 of implant 22 need not be provided with the serrations or teeth to bite into the adjacent vertebrae. This biting function can also be accomplished by providing the sides 34 with multiple steps formed in right angles from the narrowest portions at the ends 25 and 36 to the widest portion in the approximate middle of implant 22 (i.e., from the dimension W' to W to W"). Alternatively, because in the preferred embodiment shown the implant 22 is comprised of bone (see below), the surfaces of the sides 34 of implant 22 are scored, grooved, or even just "roughened up" either by the person fabricating the implant or by the surgeon at the time of implantation. Locking piece 24 can also be provided with teeth, serrations, or other structure to decrease the likelihood of extrusion of locking piece 24 from the disk space.

Those skilled in the art who have the benefit of this disclosure will recognize from the preceding paragraph that the sides 34 of implant 22 need not define an arch which is symmetrical from the end 25 to the end 36 of implant 22. Regardless, the end 25 of implant 22 is formed in a blunt, or rounded shape to reduce the likelihood of injury to the nerves of the spinal cord during insertion into the disk space.

In the embodiment shown, locking piece 24 is substantially square when viewed from the end 40 along the longitudinal axis 28. The sides of the square end 40 of locking piece 24 comprise the surfaces 50 for bearing against the bodies 12 and 14 of adjacent vertebrae 16 and 18 as also explained in more detail below. It will be recognized by those skilled in the art who have the benefit of this disclosure that the bearing surfaces 50 need not be flat and that the end 40 of locking piece 24 need not be square. Other shapes and configurations may be utilized as needed to insure that movement of locking piece 24 is resisted by the bodies of the adjacent vertebrae 16 and 18. Best results are obtained, however, when at least the vertebral bearing surface is oriented at an angle of approximately 90° to the implant bearing surface. The surfaces 42 of the locking piece 24

are substantially flat for contacting the first and second sides 32 of implant 22 to prevent rotation of implant 22 relative to locking piece 24 when locking piece 24 and implant 22 inserted into the disk space.

The purpose of the bi-planar, middle expanded, bi-convex implant 22 is to enable insertion of the implant 22 into the disk space and turning by approximately 90° to increase the disk height and stabilize the disk space. The purpose of locking piece 24 is to lock implant 22 against instability when in the vertical position, e.g., with the sides 32 parallel to the axis of the patient's spinal column, so as to maintain the disk height thereafter.

The sides 32 of implant 22 are provided with a keyway 46. Referring now to Fig. 3, an applicator for use in connection with the present invention is shown at 152 and is provided with an end 154 shaped in the form of a pair of prongs 144. The prongs 144 are formed in a size and shape substantially complementary to the size and shape of the keyway 46 of implant 22. Applicator 152 is mounted to implant 22 by inserting the prongs 144 into the keyways 46 formed on the sides 32 of implant 22. In this manner, the prongs seat the implant 22 on the end 154 of applicator 152 and resist relative rotational movement between implant 22 and applicator 152 when applicator 152 is used to rotate implant 22 in the disk space.

Although not shown in the figure, those skilled in the art who have the benefit of this disclosure will recognize that the end of the keyways 46 may be extended along the sides 32 of implant 22 further than is necessary to receive the prongs 144 on applicator 152 and that the extra length of the keyways 46 may be of gradually reducing dimension so that the prongs 144 of applicator 152 are received in a friction fit in the keyways 46 to help affirmatively mount implant 22 thereto. Other structure for achieving this same result includes a detent or serrations formed in the keyways 46. The mouth 45 of the keyway 46 on the side 32 of implant 22 at the first end 36 of the implant is wider than the width of the keyway 46 in the portion of the slot intermediate the ends 25 and 36 of implant 22 to facilatate insertion of the prongs 144 of applicator 152 into the keyway 46. The funnel-shaped portion 47 of the keyway 46 behind the mouth 45, which gradually decreases in width, acts to increase the ease with which implant 22 is mounted to applicator 152 by insertion of the prongs 144 into the

respective keyways 46 and helps to seat implant 22 thereon. Those skilled in the art who have the benefit of this disclosure will recognize that the keyway 46 may be located on the applicator 152 and a key 48 may be located on implant 22 without any difference in the manner in which those component parts function to retain implant 22 on the end 154 of applicator 152.

When the end 154 of applicator 152 is seated all the way into the keyways 46 of implant 22, so as to prevent relative rotational movement therebetween, implant 22 is inserted into the disk space and rotated therein using applicator 152 as explained below. Applicator 152 is then detached from implant 22 simply by withdrawing the applicator 152 from the disk space, the friction exerted by the adjacent vertebrae preventing the withdrawal of the implant 22. It will be apparent to those skilled in the art who have the benefit of this disclosure that the applicator 152 is of little assistance in removing the implant 22 from the disk space even if the keyways 46 of implant 22 are provided with a detent or other structure to engage the prongs 144 of applicator 152 to retain the implant 22 thereon. As noted above, in the preferred embodiment described herein, implant 22 is comprised of bone. In alternative embodiments, implant 22 is comprised of metal or inert polymeric material and, when comprised of such material, the implant may also include a bore (not shown) in the end 36 of implant 22 for receiving a complementary threaded end (not shown) on applicator 152. The advantage to using such materials is that, in the event the implant 22 needs to be removed from the disk space, an applicator of the type shown in Patent No. 5,658,336, which disclosure is incorporated in its entirety as if fully set forth herein by this specific reference thereto, is screwed into the bore to allow the implant 22 to be pulled from the disk space. If implant 22 is comprised of bone as contemplated herein and it is necessary to remove the implant 22, the implant is simply drilled out with a conventional bone drill or burr and the pieces drawn back out of the disk space with forceps or other suitable instrument to be replaced with another implant as needed.

The use of the stabilizer 10 of the present invention in, for instance, a method of lumbar intervertebral disk stabilization is illustrated in Fig. 1. Surgery is performed as in a simple diskectomy and the intervertebral disk 20 is exposed through a small laminotomy. The disk material is removed and any nerve root compression is corrected. The posterior

longitudinal ligament (not shown) and disk cartilage are removed until the surface of the bodies 12 and 14 of adjacent vertebrae 16 and 18, respectively, are exposed above and below the disk space.

Using spreaders such as those disclosed in International Application No. PCT/US95/00347, which reference is hereby incorporated into this specification in its entirety by this specific reference thereto, the vertebrae 16 and 18 are distracted to open the disk space, and once the desired "spread" is achieved, the middle portion of the disk space is packed with cancellous bone chips. Because the posterior longitudinal ligament is left intact to the opposite side and to the center of the disk space, the bone chips are held in place in the disk space.

An implant 22 having a height H and width W selected to fit the disk space is then mounted to the prongs 144 of applicator 152. The appropriately-sized implant 22 is then inserted into the disk space using the applicator 152 with the implant 22 oriented so that the top and bottom thereof, i.e., the first and second sides 32, engage the bodies 12 and 14 of adjacent vertebrae 16 and 18, respectively. Using the applicator 152, implant 22 is positioned in the disk space by anterior-posterior movement to a position in which the expanded, middle portion and the smaller width ends 25 and 36 of the third and fourth sides 34 of implant 22 contact the respective lower and upper surfaces of the bodies 12 and 14 of the adjacent vertebrae 16 and 18 when rotated by approximately 90° using the applicator 152. The respective lower and upper surfaces of the vertebral bodies 12 and 14 are slightly concave such that the larger width middle portion W" of implant 22 allows the implant 22 to engage substantially more of the respective surfaces of the vertebral bodies 12 and 14 than conventional prosthetic devices, thereby providing increased stability to the fusion once further rotation of implant 22 in the disk space is prevented as described below.

Once positioned in the disk space so as to provide maximum stabilization, the applicator 152 is then detached from the implant 22 by backing out of the incision in the patient. Locking piece 24 is then inserted through that same incision and pressed or impacted into place in the disk space adjacent and lateral to implant 22 with the implant bearing surface 42 of locking piece 24 juxtaposed and/or engaging the surface 32 of implant 22. Positioning the locking piece 24 adjacent implant 22 in this manner resists

relative rotation between implant 22 and locking piece 24. Because the bearing surfaces 50 of locking piece 24 bear against the bodies 12 and 14 of the adjacent vertebrae 16 and 18 to resist rotation of the locking piece 24 relative to the adjacent vertebrae 16 and 18 against which the bearing surfaces 50 bear, rotation of the implant 22 is also resisted. Those skilled in the art who have the benefit of this disclosure will recognize that the bearing surfaces 50 bear against the cortical end plate of the respective vertebral bodies 12 and 14, which is comprised of cortical, non-cancellous bone, and provides a hard, relatively smooth surface against which the bearing surfaces 50 bear. The end 40 of locking piece 24, which is also preferably comprised of bone, may then be shaped to different sizes and shapes (other than the square shaped end 40 shown in the figures) so as to allow the surgeon to select an appropriately size and shape that provides a close fit with the space between vertebral bodies.

If necessary, a small amount of a physiologically compatible adhesive of a type known in the art is applied over the cancellous bone chips just medial to the implant to close off the remaining portion of the opening into the disk space. The patient should be able to ambulate soon after the procedure because of the stability imparted to the spinal column by the implant of the present invention. Before narrowing of the disk space occurs, the cancellous bone chips will have started the fusion process.

The stabilizer 10 is also used to advantage to perform, for instance, a posterior lateral intertransverse fusion. The implant 22 is inserted into the region of the disk space from which a portion of the disk has been removed as described above with the locking piece 24 inserted and the posterior lateral fusion performed. Because the implant 22 provides stability to the spine until the posterior lateral fusion is solid, the patient is generally able to ambulate soon after surgery. This procedure also prevents the narrowing of the disk space, which is a common problem with posterior lateral fusion.

Referring now to Fig. 4, one preferred method for fabricating the implant 22 will now be described. Fig. 4 shows a perspective view of a cross-sectioned portion of the shaft of the human femur 200. Femur 200 is comprised of hard cortical bone 202 surrounding a central core of softer, cancellous bone 204. Implant 22 is fabricated from the cortical bone 202 of the piece of femur 200 by making a first vertical cut along the longitudinal axis of

the femur 200 in the area of the cortical bone 202 as shown at reference numeral 206 and a second vertical cut along the longitudinal axis of the femur 200 in the cortical bone 202, closer to the cancellous bone 204 in the center axis of femur 200 along the line indicated at 208. The resulting piece of the cortical bone 202 comprising the femur 200, identified by reference numeral 210 in Fig. 4 serves as a "blank" for making the implant 22. Using conventional bone saws and shaping techniques, the blank 210 is shaped to include the bi-convex first and second sides 32, rounded end 36, and so on as described above. Although the lines 206 and 208 representing the first and second vertical cuts are shown substantially parallel to each other, those skilled in the art who have the benefit of this disclosure will recognize that lines 206 and 208 need not be parallel and that there is even certain advantages to be gained by not making the cuts parallel as, for instance, when it is desired to make an implant that is wedge-shaped as described below. Those skilled in the art who have the benefit of this disclosure will also recognize that there are other bones in the body from which a piece of cortical bone can be harvested that is big enough to serve the same role as the blank 210, the femur 200 being described herein merely for the purpose of enabling the present invention as required by the Patent Statute.

Referring now to Figs. 5A and 5B, Fig. 5A is a schematic representation of the human iliac 212 and femur 200 in the area of the hip. In the presently preferred embodiment described herein, locking piece 24 is fabricated from a portion of the iliac 212. Implant 22 is fabricated from the hard cortical bone 202 of the femur 200 to give the implant 22 the strength to properly support the load of the spinal column. By contrast, because it is desired that the iliac 212 have properties that both impart strength to locking piece 24 and facilitate its fusion with the cancellous bone chips packed around the implant 22 in the disk space as well as the adjacent vertebral bodies 16 and 18, the locking piece 24 is preferably fabricated from a combination of cortical and cancellous bone and that combination is found in the iliac 212. Specifically, a first cut is made that is orthogonal to the long axis of the iliac (the latter being represented by the shadow line 216 in Fig. 5A) in the so-called "wing" of the iliac 212 as shown at line 214. A second orthogonal cut 218, substantially parallel to the first cut 214, is then made across the wing of the iliac 212 to produce a piece of bone 220 that is in effect a cross-sectional piece of the iliac. The piece

of bone 220 is then squared up at one end by cutting along the line 222. Because the cuts 214, 218, and 222 can be made in any order such that the piece of bone 220 may not be removed from the iliac 212 when cut 222 is made, cut 222 is described herein as being substantially parallel to the long axis 216 of the iliac 212.

The piece of bone 220 is shown removed from the iliac 212 and in perspective view in Fig. 5B. When viewed in this manner, it will be apparent that the piece 220 of bone harvested from the iliac 212 in the above-described manner is comprised of both hard cortical bone as shown at reference numeral 224 and softer cancellous bone as shown at 226. To make two of the locking pieces 24 of the present invention, a cut 228 is made through the piece of bone 220. Again, it will be recognized by those skilled in the art that the cut 228 can be made in any order relative to the cuts 214, 218, and 222 such that the cut 228 can be described as being substantially parallel to the cuts 214 and 218 and orthagonal to the longitudinal axis 216 of the iliac 212. The cortical bone 224 forms a relatively thin outer layer around the two sides and one end of each of the stabilizers 230A and 230B that are fabricated from piece 220, such that the stabilizer of the present invention is referred to as being "tri-cortical," and will form the implant bearing surface 50 and end 40 of stabilizer 24 as shown in Figs. 1-3. The central core of cancellous bone 226 promotes the fusion of the locking piece 24 in the disk space as described above, but is not a necessary element of the invention, it being apparent from this disclosure that a locking piece can be fabricated entirely from cortical bone or cancellous bone, the tri-cortical locking piece described herein being only a preferred embodiment of the locking piece. Those skilled in the art who have the benefit of this disclosure will also recognize that there are other bones in the body from which a piece of cortical bone can be harvested that is big enough to serve the same role as the piece 220, the iliac 212 being described herein as the source of the piece 220 for the purpose of enabling the present invention as required by the Patent Statute.

In the embodiments described herein, the implant 22 and locking piece 24 are fabricated to certain preferred dimensions, but those skilled in the art will recognize that it is desirable to fabricate them in several dimensions so as to facilitate a close fit in the disk space. For instance, a presently preferred size for implant 22 is for implant 22 to have a

height H of approximately 5 mm, a width W of about 10 mm at the ends 25, 36 increasing to a maximum of about 15 mm, and a length (along the longitudinal axis of implant 22) of about 27 mm. A locking piece 24 intended for use with an implant of this 15 X 5 X 27 size is about 10 mm X 10 mm X 27 mm. Other implant, and corresponding locking piece, sizes are also contemplated, it being understood that because they are comprised of bone in this preferred embodiment, the bone can be harvested in the desired shape and size from several locations of the skeleton.

Referring now to Fig. 6A, another embodiment of an implant constructed in accordance with the present invention is shown. Specifically, the implant 322A is substantially rectangularly shaped in cross-section and, like implant 22 in Figs. 1 – 3, is comprised of first and second sides 332 defining the height H and third and fourth sides 334 defining width W, the height dimension H being greater than the width dimension W. Third and fourth sides 334 are arched from one end of implant 322 to the other to provide the portion of implant 322 intermediate the ends 325 and 336 with a width W that is larger than the width W' and W" at the ends 325 and 336, except that the end 325 is flared as at 360 to provide the implant 322A with a width W' at the end 325 that is approximately equal to the width of implant 322A at the maximum width W. The two sides 34 therefore comprise two opposed edges, each of arched form, the opposed edges being shaped such that the end 325 is flared so that a portion of the implant 322A between the flared end part 360 and the remainder of the implant is of lesser width than the width W' of the flare 360 in the end 325 of implant 322A. This portion of lesser width of implant 322A forms upwardly and downwardly opening recesses 362 and is preferably formed as a smoothly curved recess to interact with and provide stability for the adjacent vertebrae, the articulating surfaces of which are concave in shape. As noted above in connection with the description of the embodiment shown in Figs. 1-3, implants constructed in accordance with the teachings of the present invention may be provided with means for resisting anterior-posterior movement of the implant in the disk space. In the embodiment shown in Fig. 6, implant 322 is provided with a plurality of teeth 338 for this purpose. As also noted above, the teeth near the ends of the implant may be slanted toward the ends of the implant so as to provide better contact with the adjacent vertebrae, but in the case of the implant 322 shown

in Fig. 6, it has been found that better contact is obtained by slanting the teeth in the flared portion 360 away from the end 325.

As shown in Figs. 6B and 6C, the width W' of the ends 325 of implants 322B and 322C is progressively greater than the width of implants 322B and 322C at the approximate midpoint along the longitudinal axes of implants 322B and 322C shown as the maximim width W. Stated another way, the difference in the widths W and W' of implants 322B and 322C is defined by the angle α formed by extending lines from the midpoint of the implant 322B and 322C representing width W to the tip of the flare 360 at the end 325 of each respective implant representing width W'. It is envisioned that several implants 322 would be provided with different angles α to accommodate specific patient needs; for instance, in one patient, the curvature of the spine, or lordosis, may require that an implant having an angle α that provides a width W' that is 5 mm larger than the width W be utilized between two vertebrae and that a second implant having an angle α that provides a width W' that is 10 mm larger than the width W may be needed between the next two vertebrae to maintain the proper lordosis of the spine. Of course the angle α can be any angle, but it is generally preferred that an angle α of between 0° (those skilled in the art will recognize that the angle α of the embodiment shown in Fig. 6A is 0°) and 30° will provide a sufficient range of width W' dimensions to accommodate most patient needs.

Figure 7 shows an alternative embodiment of the implant 322 shown in Fig. 6 wherein the sides 332 of the implant 322 are provided with keyways 46 having a funnel-shaped mouth 47 for receiving the prongs 144 of applicator 152 as described above. In Fig. 7, the implant 322 is provided with an angle α of 0° such that the dimensions W and W' are approximately equal, but those skilled in the art will recognize that the implant shown in Fig. 7 could have been formed with a flared end such that the angle α could have been any angle from about 0° to about 30°.

If the alternative embodiment shown in Fig. 8, is utilized, the surgeon need not select an implant having a desired angle α. Instead, the implant 422 shown in Fig. 8 is provided with a pair of blocks 464 movable relative to the implant in a direction having a component that is perpendicular to the longitudinal axis of implant 422 for changing the width W' of the flare 460 at the end 425 of implant 422. Blocks 464 are threadably

engaged to a spindle 466 that is journaled in implant 422 and means is provided, in the form of the wheel 468 integral with spindle 466, for rotating the spindle 466 to spread the blocks 464 apart, or to move the blocks 464 closer to the mid-line, or longitudinal axis, of implant 422. A track 470 is formed in implant 422, and the surface of the blocks 464 adjacent the track 470 is formed in a complementary shape (not shown) for engaging the track 470 to define the direction of in which the blocks 464 slide along track 470 relative to implant 422. Those skilled in the art who have the benefit of this disclosure will recognize that the direction of movement of blocks 464 relative to implant 422 need not be perpendicular to the longitudinal axis of implant 422 and that it may even be advantageous to move blocks 464 in a direction defined by an angle that is not a 90° angle relative to the longitudinal axis of implant 422. For this reason, the movement of the blocks 464 is described herein as being in a direction "having a component that is perpendicular" to the longitudinal axis of implant 422 rather than in a direction that is perpendicular to the longitudinal axis of implant 422.

Although described in terms of the preferred embodiment shown in the figures, this embodiment is shown to exemplify the present invention, it being recognized by those skilled in the art that certain changes can be made to the specific structure of the preferred embodiment shown and described without departing from the spirit of the present invention. In the case of one such change, the first and second sides of the implant are substantially flat but not parallel along their longitudinal axes so that the implant is wedge-shaped. The wedge shape of the implant facilitates insertion of the implant into the disk space, the rounded end of the implant reducing the likelihood of injury to the nerves of the spinal cord during insertion into the disk space. Likewise, the width at one end of the implant can be less than the width at the end, both widths, however, being less than the width in the middle, expanded portion of the implant. All such modifications, and other modifications which do not depart from the spirit of the present invention, are intended to fall within the scope of the following claims.

WHAT IS CLAIMED IS:

1. Apparatus for fusion of adjacent vertebrae comprising:

an elongate implant having a minimal height defined by first and second sides and a maximal width defined by third and fourth sides, the third and fourth sides being arched from one end of said implant to the other; and

a locking piece comprising (a) an implant bearing surface for engaging either the third or fourth sides of said implant to resist rotation of said implant relative to said locking piece after said implant is inserted into the disk space between two adjacent vertebrae with the first and second sides of said implant contacting the bodies of the adjacent vertebrae and then rotated so that the third and fourth sides of said implant contact the adjacent vertebrae when said locking piece is positioned in the disk space, and (b) a vertebral body bearing surface for engaging the body of the adjacent vertebrae when said locking piece is positioned in the disk space to resist rotation of said locking piece in the disk space.

2. The apparatus of claim 1 wherein said implant is provided with a keyway for receiving the prongs of an applicator for inserting said implant into the disk space and rotating said implant in the disk space.

3. The apparatus of claim 1 wherein the keyway is provided with a funnel-shaped portion, the width of the funnel-shaped portion decreasing to the width of said keyway.

4. The apparatus of claim 2 additionally comprising an applicator comprised of an elongate handle and a head, said head having a pair of prongs formed thereon shaped to fit into and engage the funnel-shaped portions of said keyways.

5. The apparatus of claim 1 wherein said implant and said locking piece, or said implant or said locking piece, are comprised of bone.

6. The apparatus of claim 1 wherein said locking piece is comprised of a central core of cancellous bone having a layer of cortical bone surrounding at least a portion of the central core.

7. The apparatus of claim 1 wherein at least two sides of said locking piece are substantially parallel.

8. The apparatus of claim 7 wherein said locking piece is comprised of a central core of cancellous bone surrounded by a layer of cortical bone on three sides.

9. The apparatus of claim 1 wherein said implant is comprised of cortical bone.

10. The apparatus of claim 1 wherein one end of said implant is flared so that the first and second sides of said implant extend to a height equal to or greater than the maximal height of said implant.

11. Apparatus for use in fusing adjacent vertebrae comprising:

an elongate implant having a height defined by first and second sides and a width defined by third and fourth sides, the height of said implant being greater than the width of said implant, the third and fourth sides being arched from one end of said implant to the other, said implant having one end flared for maximizing the width of said implant at said flared end;

a locking piece comprising an implant bearing surface for engaging the third or fourth sides of said implant to resist rotation of said implant about the longitudinal axis thereof after said implant is inserted into the space between two adjacent vertebrae and then rotated so that the third and fourth sides of said implant contact the adjacent vertebrae and said locking piece is positioned in the disk space with the implant bearing surface engaging the third or fourth sides of said implant and a vertebral body bearing surface for engaging the body of the adjacent vertebrae when said locking piece engages said implant to resist rotation of the locking piece in the disk space.

12. The apparatus of claim 11 wherein the flared end of said implant is comprised of one or more blocks movable relative to said implant in a direction having a component substantially perpendicular to the longitudinal axis of said implant for changing the width of the flared end of said implant.

13. The apparatus of claim 12 wherein said blocks are threadably engaged to a spindle journaled in said implant and means is provided for rotating said spindle.

14. The apparatus of claim 11 wherein the first and second sides of said implant are provided with means at the flared end for resisting movement of said implant relative to the adjacent vertebrae in a direction along the longitudinal axis of said implant.

15. The apparatus of claim 1 wherein the vertebral body bearing surface of said locking piece is oriented at approximately 90° to the implant bearing surface.

16. An apparatus for use in fusing adjacent vertebrae, the apparatus comprising an elongate implant with two opposed substantially planar faces, and with two opposed edges each being arched from one end of the implant to the other and a locking piece dimensioned to be located adjacent a single one of said planar faces and to prevent rotation of the implant and the locking piece are inserted into a space between two vertebrae.

17. An apparatus according to claim 16 wherein the opposed faces are substantially parallel.

18. An apparatus according to claim 16 wherein the opposed faces are inclined so that the element is of tapering form.

19. An apparatus according to any one of claims 16-18 wherein the element is of symmetric form, having relatively narrow ends, and a relatively wide central portion defined by the arched opposed edges.

20. An apparatus according to any one of claims 15-19 wherein the opposed arched edges are toothed, scored, grooved or otherwise roughened.

21. An apparatus according to any one of claims 15-20 wherein the locking piece is an elongate piece of substantially square or rectangular section.

22. An apparatus according to any one of claims 15-22 wherein the locking piece has teeth, serrations, grooves or other roughening on surfaces thereof.

23. An apparatus according to any one of claims 15-22 wherein at least one of the implant and the locking piece are made of bone.

24. An apparatus according to claim 23 wherein the locking piece is comprised of a central core of cancellous bone having a layer of cortical bone surrounding at least a portion of the central core.

25. An apparatus according to claim 24 wherein the locking piece is of substantially square or rectangular cross section, and the cancellous bone central core is surrounded by a layer of cortical bone on three sides of said cross section.

26. An apparatus according to any one of claims 23-25 wherein the implant is formed of cortical bone.

27. An apparatus according to any one of claims 16-26 wherein the implant is provided with keyways to receive the prongs of an applicator.

28. An apparatus according to claim 27 wherein the keyways are formed in the planar faces and extend axially of the implant.

29. An apparatus according to claim 27 or 28 wherein each keyway is provided with a funnel shaped terminal portion, the funnel shaped portion converging to a width approximately equal to the width of the main part of the keyway.

30. An apparatus according to any one of claims 27-29 further comprising an applicator having prongs adapted to co-operate with said keyways.

31. A method of making an apparatus according to any one of claims 16-30 comprising the steps of forming a "blank" from cortical bone of the femur between two axial substantially parallel cuts, and forming the insert from the blank.

32. A method of making an apparatus according to any one of claims 16-30 wherein the locking piece is made by cutting the locking piece from the iliac area of the hip.

33. An apparatus for use in fusing adjacent vertebrae, the apparatus comprising an elongate implant to be located between adjacent vertebrae, the implant being of elongate form and having two opposed edges, each of arched form, the opposed edges being such that an end part of the implant is flare dso that a portion of the implant between the flared end part and the remainder of the implant is of lesser width that the width of the flare.

34. An apparatus according to claim 33 wherein the arched edges and flare form an upwardly open recess in the top part of the implant and a downwardly open recess in the bottom part of the implant, the recesses being smoothly curved recesses.

35. An apparatus according to claim 34 wherein the recesses are substantially symmetrical about a horizontal plane dividing the upper and lower parts of the implant.

36. An apparatus according to any one of claims 33-35 wherein the flared end part of the implant is constituted by at least one block which is novably mounted on the rest of the implant for changing the width of the implant at the flared end part thereof.

37. In apparatus according to claim 36 wherein there are two said blocks, each slidably mounted to the rest of the implant.

38. An apparatus according to claim 36 wherein there are two said blocks, each slidably mounted to the rest of the implant.

39. An apparatus according to claim 35 or 37 wherein the or each block is threadedly engaged with a rotatable spindle, the spindle being mounted on the rest of the implant, means being provided to rotate the spindle.

40. An apparatus according to claim 39 wherein the implant has two opposed substantially planar faces.

41. An apparatus according to claim 39 wherein the keyways are formed in the planar faces and extend axially of the implant.

42. An apparatus according to claim 40 or 41 wherein each keyway is provided with a funnel shaped terminal portion, the funnel shaped portion converging to a width approximately equal to the width of the main part of the keyway.

43. An apparatus according to any one of claims 40-42 further comprising an applicator having prongs adapted to co-operate with said keyways.

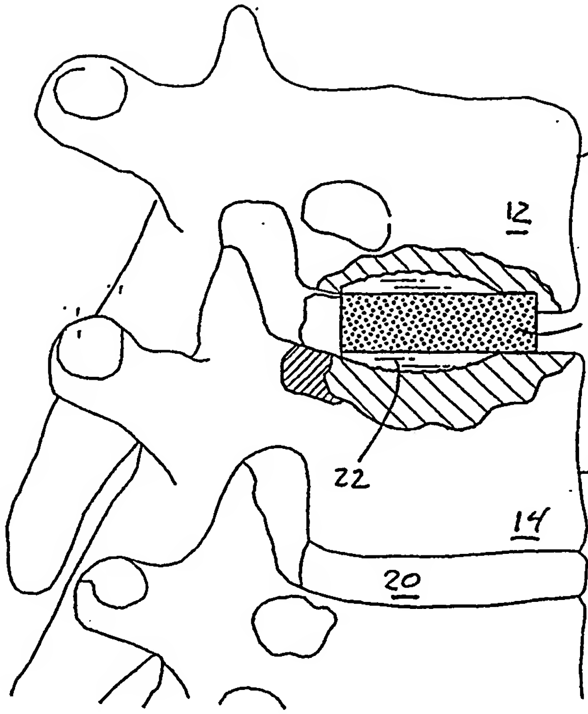

Fig. 1

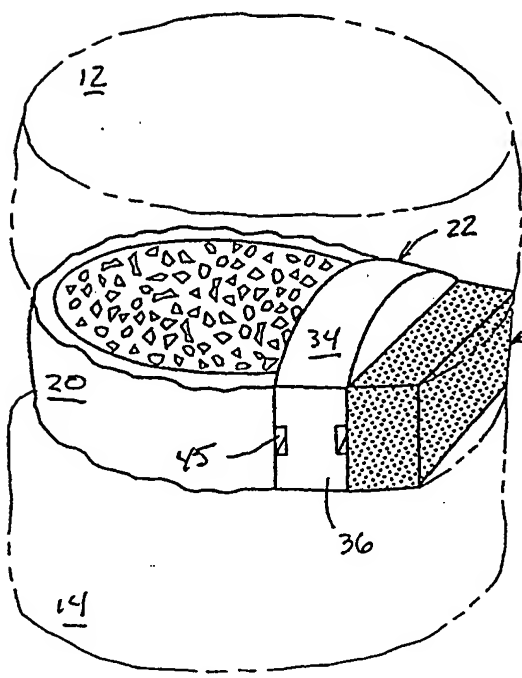

Fig. 2

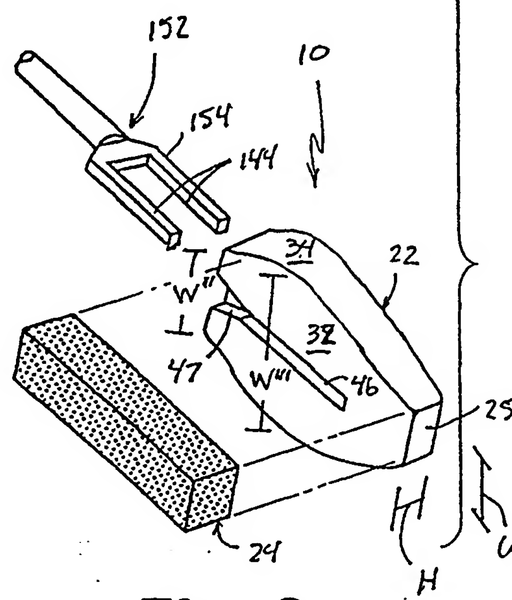

Fig. 3

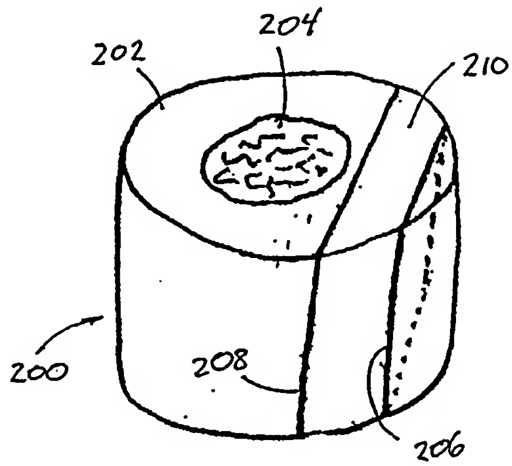

Fig. 4

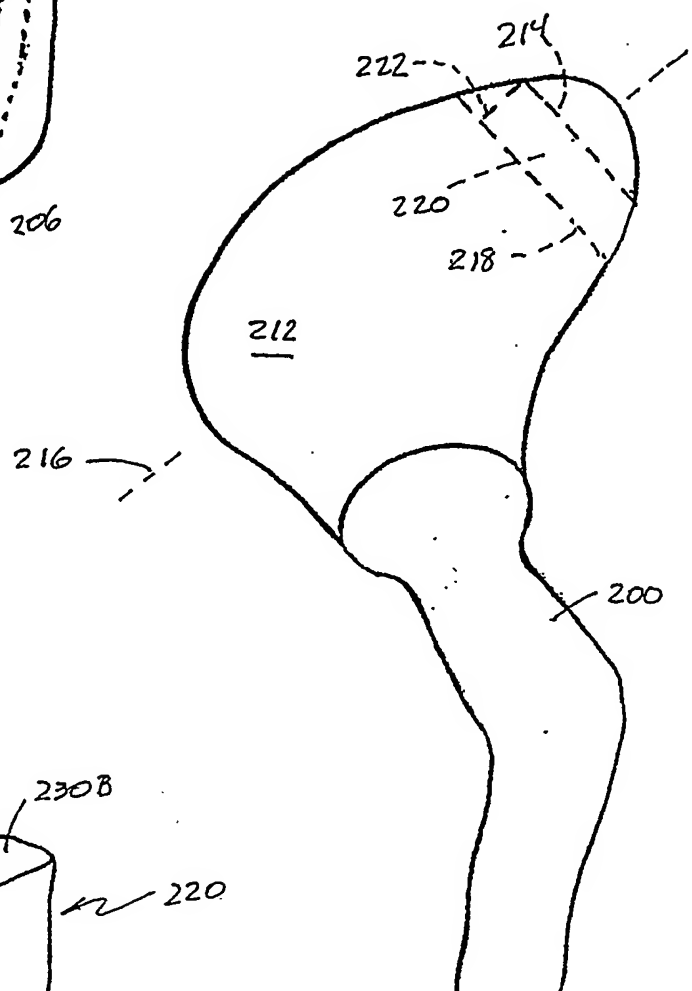

Fig. 5A

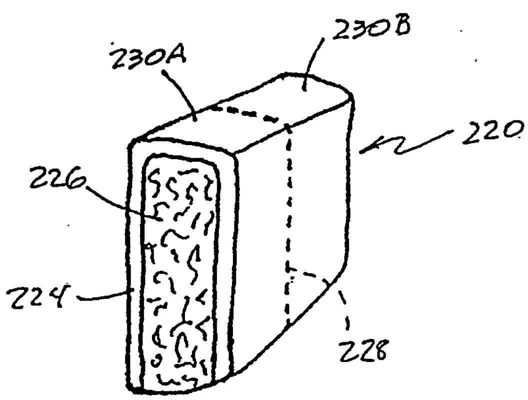

Fig. 5B

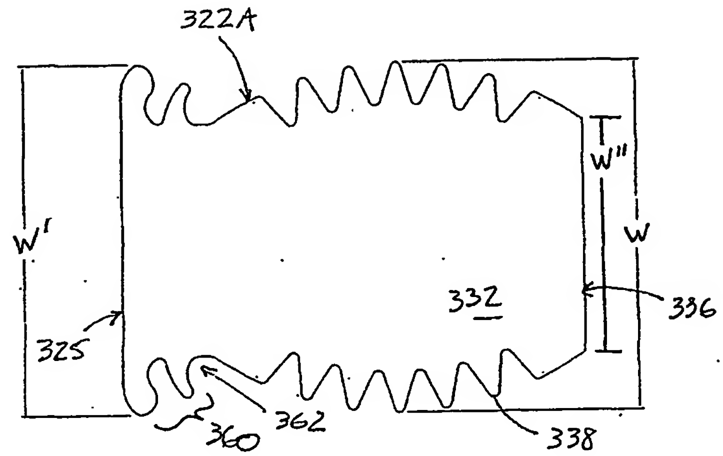

FIG. 6A

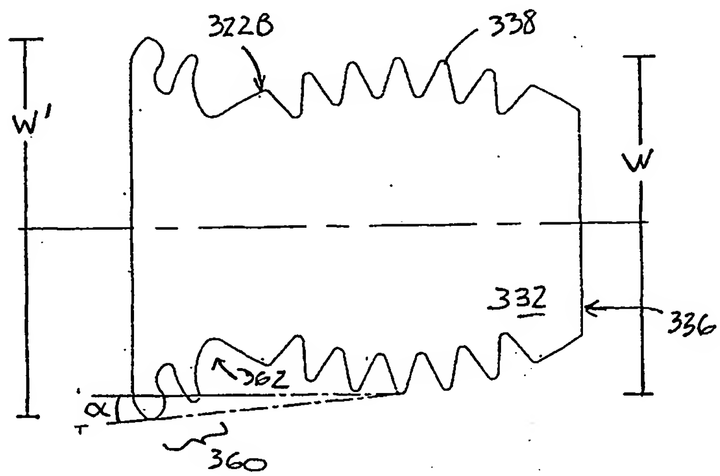

FIG. 6B

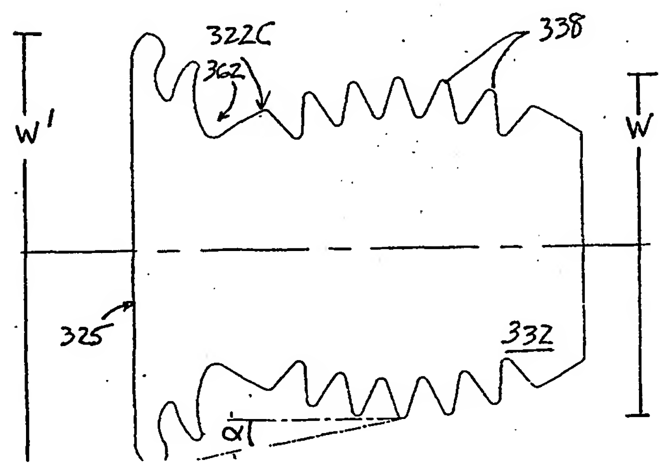

FIG. 6C

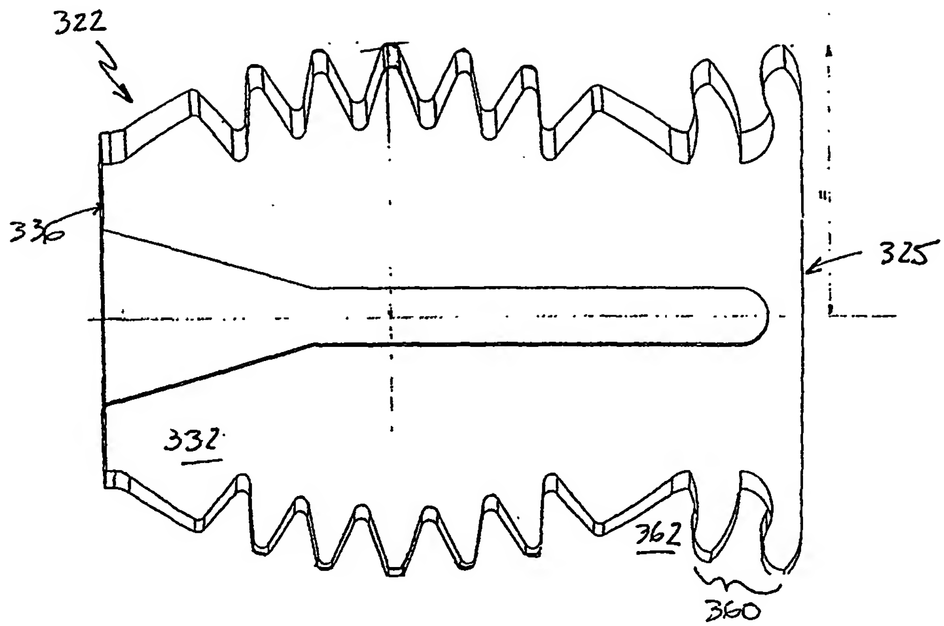
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FIG. 7

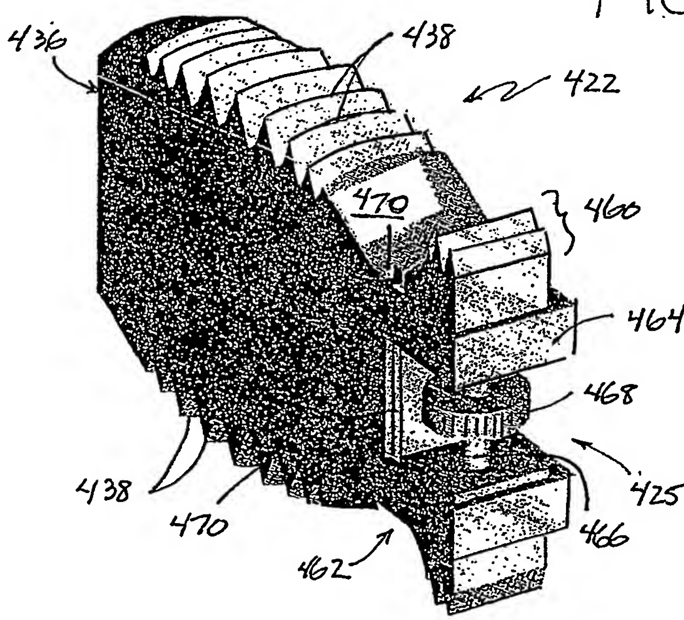
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FIG. 8

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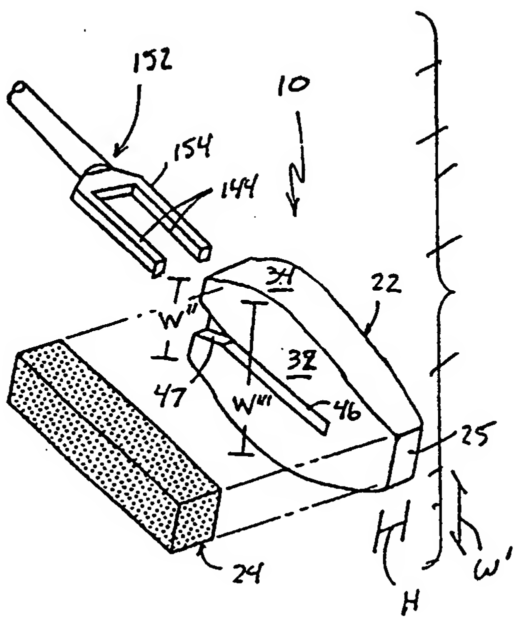
[Continued on next page]

(54) Title: ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER



(57) Abstract: A middle expanded, removable disk implant for stabilizing adjacent vertebrae. The implant is substantially rectangular in cross-sectional shape with a minimal height and a width greater than the height. The implant is detachably mounted to an applicator for insertion into the space between two adjacent vertebrae from which a portion of the intervertebral disk has been removed. Once inserted, the implant is positioned by anterior-posterior movement in the disk space to the position in which both the expanded, larger width middle portion and the smaller end portions engage the bodies of the adjacent vertebrae and the implant is then rotated to bring the sides of the rectangularly-shaped implant defining the width of the implant, with its larger dimension, into engagement with the bodies of the vertebrae. A locking piece is then inserted into the disk space adjacent the rotated implant. The locking piece includes a surface for bearing against the bodies of the adjacent vertebrae to resist rotation of the locking piece along the longitudinal axis thereof and an implant bearing surface for engaging one of the sides of the implant defining the width of the implant to resist rotation of the implant relative to the locking piece. Both implant and locking piece are comprised of bone, the locking piece being preferably comprised of both cortical and cancellous bone, or the implant is comprised of metal, bio-compatible polymer, or other suitable material. The implant may also include a flared end for maintaining proper spinal curvature of the patient.

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International Application No
PCT/US 01/13824

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 658 336 A (PISHARODI MADHAVAN) 19 August 1997 (1997-08-19) cited in the application claims; figures	1,7,11, 15-22,33
X	US 5 893 890 A (PISHARODI MADHAVAN) 13 April 1999 (1999-04-13) cited in the application claims; figures	1,7,11, 15-22,33
X	WO 96 40016 A (PISHARODI MADHAVAN) 19 December 1996 (1996-12-19) cited in the application	1,7,11, 15-22,33
A	claims; figures	34-39

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[X] Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
5 February 2002	13/02/2002

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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